

Remarks

The Office Action mailed June 10, 2009 has been received and reviewed. Claims 39, 41, and 43-45 have been amended. No claims have been canceled or added by this response. Therefore, the pending claims are claims 39-41 and 43-45. However, claim 40 has been withdrawn from consideration by the Examiner. As such, the remarks provided herein are made with regard to claims 39, 41, and 43-45. Reconsideration and withdrawal of the rejections are respectfully requested in view of the amendments and remarks provided herein.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 39, 41, and 43-45 under 35 U.S.C. §103(a) as being unpatentable over Okada et al. (U.S. Patent No. 5,672,158) in view of Fandetti et al. (U.S. Patent No. 3,645,562) and further in view of Hamilton et al. (U.S. Patent No. 1,738,996). Applicants respectfully traverse the Examiner's rejections.

However, without prejudice, Applicants have amended the claims to include limitations similar to those suggested by the Examiner (see Response to Arguments, page 6, pending Office Action). The amendment of claim 39 is intended to clarify the "elongation" term in the claim. However, it is believed that the scope of the claim is intended to be the same after the amendment as it was before the amendment. The other claims and claim 39 were also amended to correct for various formalities, e.g., lack of antecedent basis.

To establish a *prima facie* case of obviousness, there must be a finding that the prior art included each element claimed, although not in a single prior art reference. See M.P.E.P. § 2143.

Okada et al., Fandetti et al., and Hamilton et al. do not describe, teach or suggest all the elements of claim 39.

For example, Applicants have previously argued that claim 39 specifies an *elongated* outer tubular body having a lumen and an elongated inner tubular member nested within the lumen of the *elongated* outer tubular body. The Examiner alleges that Akada et al. shows in Fig. 9 (shown below) an elongated outer tubular body 33 having a lumen with an inner surface provided with an inwardly directed projection and an elongated inner tubular member 32

coaxially nested within the lumen of the outer tubular body 33 and having an outer surface provided with outwardly directed projections.

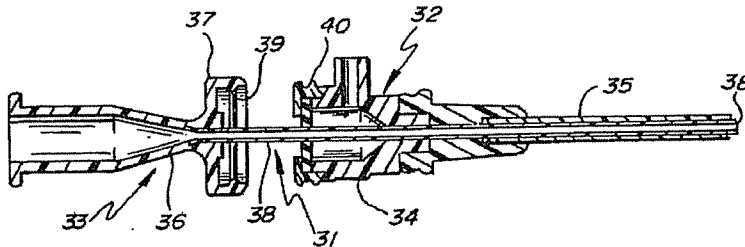


Fig. 9.

However, as is evident from Figure 9, the sheath section 32 is not an “inner elongated tubular member” coaxially nested within the lumen of an “elongated outer tubular body” (i.e., alleged by the Examiner to be the dilator section 33). The Examiner continues to allege that previous arguments with respect to the “elongated” term were not persuasive since the term “elongated” does not imply a specific length for the structure and therefore, the previously presented claims do not “preclude the examiner from interpreting the entire element 33 as the elongated outer tubular body as the claim merely requires that the elongated outer tubular body has a lumen, and wherein the inner tubular member is nested within this lumen.” The Examiner further alleges that “[t]he claim does not specify that the lumen has to extend from the proximal end to the distal end defining a length therebetween, and wherein the inner tubular member is nested within the entire length of the lumen of the elongated outer tubular member.” (see Response to Arguments; page 6, pending Office Action).

Claim 39 has been amended to clarify the “elongation” terminology and the nesting of the inner tubular member in the lumen of the outer tubular body as suggested by the Examiner (e.g., precluding interpretation set forth by the Examiner). For example, claim 39 recites that the elongated outer tubular body having proximal and distal ends includes a lumen extending from the proximal end to the distal end with an inner surface. Further, for example, claim 39 has been amended to recite that the elongated inner tubular member is coaxially nested within the lumen

of the outer tubular body from at least the proximal end of the outer tubular body to the distal end thereof.

In view of such clarification in amended claim 39, Okada et al. cannot be read so broadly as to allege that it describes, teaches or suggests the structure of the elongated inner tubular member and its nested position within the lumen of the elongated outer tubular body. As such, the structural arrangement recited in amended claim 39 is not shown by Okada et al.

Further, for example, Okada et al. does not describe that the elongated inner tubular member be nested within the lumen of the elongated outer tubular body to longitudinally move and rotate therein as is also recited in claim 39. By identifying the dilator section 33 as the outer tubular body and the sheath section 32 as the inner tubular member, the limitation that the elongated inner tubular member be nested within the lumen of the elongated outer tubular body to longitudinally move and rotate therein as recited in claim 39 is necessarily absent from Okada et al. Rather, the dilator 38 of the dilator section 33 (i.e., alleged to be the outer tubular body) is nested within the sheath 35 of the section 32 (i.e., alleged to be the inner tubular member). This is quite the opposite of the structure recited in claim 39.

Further, clearly, once sheath hub 34 of sheath section 32 with groove 40 is snapped into place within flange 37 of dilator hub 36 of the dilator section 33, there is no longitudinal or rotational movement of sheath hub 34 within dilator hub 36. Moreover, Okada describes this in detail and without question at column 4, lines 46-65. In fact, the structure of Okada et al. (e.g., the flange 37 and groove 40 are expressly designed to restrict relative rotation or axial movement). See col. 4, lines 54-55 (“... it does not happen that the dilator section 33 and the sheath section 32 rotate relatively or are displaced in the axial direction . . .”).

Fandetti et al. and Hamilton et al. are only used by the Examiner to show locking mechanisms and/or frustoconical flanges, and they do not cure the deficiencies of Okada et al. Therefore, the cited references do not teach all the limitations of claim 39 and for at least this reason alone, claim 39 is not obvious in view of the cited references.

Amendment and Response

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For: METHOD AND APPARATUS FOR PROVIDING INTRA-PERICARDIAL ACCESS

As claims 41 and 43-45 depend on claim 39, either directly or indirectly, they include all the limitations of claim 39. As such, for the same reasons as set forth herein with respect to claim 39, dependent claims 41 and 43-45 are also not obvious over the references cited.

It is respectfully requested that the rejections of claims 39, 41, and 43-45 be withdrawn.

Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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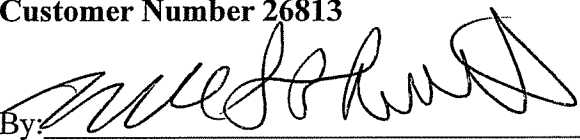
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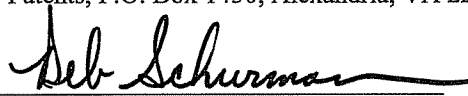
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12th day of October, 2009.

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